

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SUNOVION PHARMACEUTICALS INC., :

Plaintiff, :

v. : Civil Action No. 06-113-LPS

DEY PHARMA., L.P., DEY, INC., :

MYLAN INC., and MYLAN :

PHARMACEUTICALS INC., :

Defendants. :

Thomas H. Beck, Esquire and Neal K. Dahiya, Esquire of SIDLEY AUSTIN LLP, New York, NY. Paul J. Zegger, Esquire of SIDLEY AUSTIN LLP, Washington, DC.
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Attorneys for Defendants.

MEMORANDUM OPINION

January 18, 2012
Wilmington, Delaware.



STARK, U.S. District Judge:

I. INTRODUCTION

Presently before the Court is the issue of incorporation by reference, which the parties have raised in connection with Defendants' affirmative defense and counterclaim alleging that the patents-in-suit are invalid for anticipation. For the reasons set forth below, the Court agrees with Defendants that the host document, British patent GB 1 298 494, incorporates by reference the practical utility of the compounds described in the specification of British patent GB 1 200 886. Accordingly, that material will be considered together as a single reference for purposes of anticipation at trial, which is scheduled to begin on January 30, 2012.

II. BACKGROUND

The present litigation is a Hatch-Waxman patent infringement suit brought by Plaintiff Sunovion Pharmaceuticals Inc. ("Sunovion") in response to Defendants' application for FDA approval to market generic levalbuterol. Defendants contend that the patents-in-suit are invalid for anticipation in view of a British patent, GB 1 298 494 ("the GB '494 patent"), which they contend incorporates by reference additional material separately described in another British patent, GB 1 200 886 ("the GB '886 patent"). In 2009, the parties filed cross-motions for summary judgment on the issue of anticipation. Judge Farnan, then presiding over the case, issued an opinion and order denying Sunovion's motion and granting in part and denying in part Dey's motion. (D.I. 392; D.I. 393) Judge Farnan "reserve[d] decision on the issue of whether and to what extent GB '494 incorporates by reference[] GB '886." (D.I. 392 at 15 n.3) The parties subsequently re-briefed the issue of incorporation by reference pursuant to this Court's November 23, 2011 Order. (D.I. 475; D.I. 477; D.I. 487; D.I. 489)

III. LEGAL STANDARDS

Anticipation requires that the four corners of a single prior art document describe every element of the claimed invention, either expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation. *See Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347 (Fed. Cir. 1999).

Material not explicitly contained in a single prior art document may still be considered for purposes of anticipation if that material is incorporated by reference into the document. *See Ultradent Prods., Inc. v. Life-Like Cosmetics, Inc.*, 127 F.3d 1065, 1069 (Fed. Cir. 1997). Incorporation by reference provides a method for integrating material from various documents into a host document by citing such material in a manner making clear that the material is effectively part of the host document as if it were explicitly contained therein. *See Advanced Display Sys., Inc. v. Kent State Univ.*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates, and clearly indicate where that material is found in the various documents. *See id.*¹

Whether and to what extent material has been incorporated by reference into a host document is a question of law. *See Advanced Display*, 212 F.3d at 1283. If an anticipation

¹*See also Northrop Grumman Information Tech., Inc. v. U.S.*, 535 F.3d 1339, 1344 (Fed. Cir. 2008) (stating incorporation by reference in contract law requires “language that is **express** and **clear**, so as to leave no ambiguity about the identity of the document being referenced, nor any reasonable doubt about the fact that the referenced document is being incorporated into the contract”). Although incorporation by reference is a concept common to both patent and contract law, it is unclear whether or to what extent the *Northrop Grumman* standard applies in the patent context. Because the parties agree that the standard articulated in *Advanced Display* governs the present dispute (*see* D.I. 477 at 1-2; D.I. 475 at 4, 6; D.I. 520 at 6:12-14 and 18:16-19), the Court will apply their agreed-upon standard.

determination implicates incorporation by reference, the court's role is to determine what material in addition to the host document constitutes the single reference. The factfinder's role, in turn, is to determine whether that single reference describes the claimed invention. *See id.*

IV. DISCUSSION

As noted, the parties' dispute concerns whether the GB '494 patent adequately incorporates by reference the practical utility of the racemic compounds separately described in the GB '886 patent, such that the pertinent material from both patents properly can be considered together as a "single reference" for anticipation. Dey concedes that its sole anticipation defense is viable only if the Court finds in its favor on the issue of incorporation by reference. (D.I. 473 at 65:19-25)

As reproduced below, the GB '494 patent states in relevant part:

This invention is concerned with a process for the preparation of optical enantiomers of certain 1-phenyl-2-aminoethanol derivatives which are described in particular in our United Kingdom Specification No. 1,200,886.

In our said United Kingdom Specification No. 1,200,886 there are described phenylaminoethanol derivatives which may stimulate β -adrenergic receptors . . . ***The practical utility of such activity is more fully described in said specification.***

The phenylaminoethanol derivatives (I) may exist in two optically isomeric forms and according to the invention we have discovered a new process for the preparation of such isomers; the advantage of this process is that it facilitates the production of pure isomers. This is of particular importance in this case since the pharmacological activity of one isomer in standard tests for bronchodilator action is very much greater than that of the other.

(GB '494 patent at 1:9-34) (emphasis added).

Sunovion contends that this passage does not satisfy the legal standard for incorporation by reference because the GB '494 patent is directed to an entirely different invention that merely refers to the GB '886 patent as background, and "not as part of the substantive description of the

invention.” (D.I. 477 at 3) Sunovion further contends that the GB ’494 patent fails to identify “with detailed particularity what specific material it incorporates” and likewise does not “clearly indicate where that material is found” in the GB ’886 patent. (*Id.* at 5)

Defendants respond that the GB ’494 patent satisfies the requirements for incorporation by reference because it adequately describes with detailed particularity the specific material incorporated (i.e., the practical utility of the racemic compounds’ pharmacological activity) and also clearly indicates where that material is found (in the specification of the GB ’886 patent). (D.I. 475 at 4)

Although a close question, on balance the Court agrees with Defendants that the GB ’494 patent adequately incorporates by reference the practical utility of the compounds described in the GB ’886 patent. The Federal Circuit has held that analogous statements containing similar levels of detail were sufficiently specific for incorporation by reference. *See Callaway Golf Co. v. Acushnet Co.*, 576 F.3d 1331, 1345-47 (Fed. Cir. 2009) (“Reference is made to . . . U.S. Pat. No. 4,274,637 which describes a number of foamable compositions of a character which may be employed . . . for the golf balls of this invention.”); *In re Voss*, 557 F.2d 812, 816-17 (CCPA 1977) (“Reference is made to United States Patent No. 2,920,971 . . . for a general discussion of glass-ceramic materials and their production.”); *In re Hughes*, 550 F.2d 1273, 1275-76 (CCPA 1977) (“Reference is made to application Ser. No. 131,108 for complete descriptions of methods of preparing aqueous polymeric dispersions applicable in the hereinafter described invention.”); *cf. Commonwealth Sci. & Indus. Research Org. v. Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1372 (Fed. Cir. 2008) (finding no incorporation by reference where host document merely cited

another document in footnote without any further explanation or discussion).² In view of this precedent, the Court finds that the GB '494 patent adequately references the GB '886 patent with sufficiently "detailed particularity" regarding the practical utility of the compounds disclosed in the GB '886 patent.

The Court disagrees with Sunovion's assertion that the GB '494 patent refers to the compounds' practical utility merely as "background" and "not as part of the substantive description of the invention." (D.I. 477 at 3) To the contrary, the GB '494 patent makes clear that the practical utility of the compounds described in the GB '886 patent is an integral aspect of the invention claimed in the GB '494 patent. Specifically, the GB '494 patent notes that the racemic compounds of the GB '886 patent "stimulate β -adrenergic receptors" and that "the practical utility of such activity is more fully described" in the specification of the GB '886 patent. (GB '494 patent at 1:18-22) Immediately thereafter, in the next paragraph, the inventor emphasized that the invention involved the discovery of a new process for preparing the individual isomers of albuterol, and that "the advantage of this process . . . is of particular importance . . . since the pharmacological activity of one isomer in standard tests for bronchodilator action is very much greater than that of the other." (*Id.* at 1:25-34) The inventor thus clearly indicated that the claimed process for preparing isomers was advantageous and important precisely because the pharmacological activity – and, in turn, the practical utility – that is more fully described in the GB '886 patent was "very much greater" for one isomer

²Although the GB '494 patent does not specifically use the phrase "incorporate by reference," the cases cited above illustrate that those specific words are not required. Moreover, the Federal Circuit has indicated that "no particular 'magic words' are required to incorporate a document by reference." *Northrop Grumman*, 535 F.3d at 1346. Instead, what is required is that the applicant "cit[e] such material in a manner that makes clear that the material is effectively part of the host document as if it were explicitly contained therein." *Advanced Display*, 212 F.3d at 1282.

compared to the other. By clearly linking in this manner the “advantage” and “importance” of the claimed invention of the GB ’494 patent to the “practical utility” of the pharmacological activity described in the GB ’886 patent, the inventor “cit[ed] such material in a manner that makes clear that the material is effectively part of the host document,” and thereby incorporated by reference the GB ’886 patent’s description of practical utility. *Advanced Display*, 212 F.3d at 1272.

The Court’s conclusion is further supported by additional factors. The GB ’886 patent is the only prior art document referenced in the GB ’494 patent. Additionally, the GB ’886 patent is prominently discussed right at the outset of the GB ’494 patent (in connection with the inventor’s view of what “[t]his invention is concerned with”). (GB ’494 patent at 1:1-35) Moreover, both the GB ’494 patent and GB ’886 patent are owned by the same entity, Allen & Hansbury’s Limited.³

Sunovion has raised various arguments asserting why, in its view, the GB ’886 patent does not adequately disclose the practical utility of levalbuterol as it specifically pertains to the claimed inventions of the patents-in-suit. (D.I. 487 at 1-2) The Court’s role, however, is limited to determining what material in addition to the host document constitutes the single reference for anticipation purposes; whether that single reference actually anticipates the asserted claims is a

³These circumstances distinguish the present case from other cases finding no incorporation by reference. See, e.g., *Commonwealth Sci. & Indus. Research Org.*, 542 F.3d at 1372 (no incorporation by reference where document was cited only in a footnote without discussion or explanation); *Medtronic Vascular Inc. v. Abbott Cardiovascular Sys., Inc.*, 614 F. Supp. 2d 1006, 1020 (N.D. Cal. 2009) (no incorporation by reference where document was referenced in connection with only one of several drawings rather than the invention as a whole); *Telcordia Techs., Inc. v. Lucent Techs., Inc.*, 514 F. Supp. 2d 598, 611 (D. Del. 2007) (no incorporation by reference where host document distinguished the referenced material rather than emphasizing its importance); *SRI Int’l, Inc. v. Internet Sec. Sys.*, 456 F. Supp. 2d 623, 627 (D. Del. 2006) (no incorporation by reference where host document cited a total of twenty-four other documents).

determination for the factfinder to resolve at trial.⁴

V. CONCLUSION

For the foregoing reasons, the Court concludes that the GB '494 patent incorporates by reference the practical utility of the compounds described in the specification of the GB '886 patent, and that such material will be considered as a single reference for purposes of anticipation at trial. An appropriate Order follows.

⁴The parties have also cited to testimony provided by an inventor and an author of the incorporating host reference. The subjective views of these individuals are not helpful in resolving the dispute presently before the Court, since it is the objective standard of "one reasonably skilled in the art [that] should be used to determine whether the host document describes the material to be incorporated by reference." *Advanced Display*, 212 F.3d at 1283. Similarly, the expert testimony cited by Sunovion is largely directed not to the issue of incorporation by reference but, rather, to the merits of the ultimate anticipation determination, and for this reason is generally unhelpful here.